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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022.476	12/18/2001	Jonah Shacknai	00-40175-US-P	4300

7590

03/22/2005

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EXAMINER

LEVY, NEIL S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/022,476	Applicant(s) SHACKNAI ET AL.	
	Examiner Neil Levy	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-117 is/are pending in the application.
- 4a) Of the above claim(s) 4,9,13,15,20,21,24-27 and 30-115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,10,12,14,16-19,22,23,27,28,116 and 117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10 and 12-117 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/05/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4, 9, 13, 15, 20, 21, 24-27, 30 – 115 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/3/04.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14 depends on cancelled 11.

Claims 13, 10, 12, 14, 17-19, 22, 23, 28, 29, 116 and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al – 6429,231 in view of remarks of 11/23/04, Bonnar et al '93 and further in view Robinson '39 or Merck '72.

The rejection of record is maintained, but with explanatory support for the now amended claim language requiring mites on human skin. Applicant avows p. 15 that almost all-adult skin has some mites. Bhagwat applies preparations consisting essentially of sulfur and sulfacetamide, as active ingredients (example 2, 5% S, 10% sulfacetamide, the only instant actives, as a Lotion, applied to human skin, to treat dermatological disorders (col. 1, Summary). Although examples are given, mites are not mentioned, but cutaneous infections, and inclusion of antimicrobial agents, sodium sulfacetamide, are taught at col. 2, with added sulfur. The compositions are used in methods for treatment of dermatological conditions (col. 5, lines 18-27 and 44-56).

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"As used herein, "dermatological disorder" refers to any disorder of skin, hair, or glands. A dermatological disorder can be manifest in the form of visible lesions, per-
emergent lesions, pain, sensitivity to touch, irritation, inflammation, or the like.

Dermatological disorder include disorders of the cutaneous and pilosebaceous unit or the process of kerato genesis. For example, a dermatological disorder can be disorder of the epidermis or dermis, or within and surrounding the pilosebaceous follicle, which is located within the skin's epidermis, dermis, or both. Examples of dermatological disorders include hyperpigmented skin, cutaneous infections, and the like. "Since mites are always present (applicant and Bonnar) on human skin, any disorder, manifested as indicated, would be treatable by Bhagwat's methods. Application of sulfur and sulfacetamide in a dermatologically acceptable carrier.

Robinson provides one example of applicants' reiterated request for proof of a tie in of mite infestation with any of the skin disorders recited by the prior art record. At the section "How Scabies may simulate enzema" (p. 638) we see the itchy, abraded skin favors infection by bacteria, leading to pustules, enzema, boils. Treatment is indicated to be application of sulfur (Top, P.638); it's prepared in a dermatologically-accepted carrier. Repeated washings are necessary. Merck (top, p. 1455) also discloses that mites cause itching, resulting in cutaneous dermatitis, eczema; and bacterial infection. A sulfate is useful for the secondary bacterial inflammation (treatment, p. 1455). P. 1736 (mites) in indicates local prurities.

Bhagwat do not teach the sources of the various dermatological and cutaneous disorders they treat, but we see a multitude of references, exemplified by Robinson and

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Merck, which show that these disorders can be either caused by or associated with the presence of mites on human skin. Applicant and Bommar state that mites are almost always present on human skin. It would have been obvious to a person of ordinary skill in the dermatological art at the time the invention was made desiring to control and remediate visible lesions, irritation, inflammation, or the like dermatological disorders and cutaneous infections, to utilize the methods of Bhagwat – application of sulfur and sodium sulfacetamide in dermatologically acceptable carriers. Bhagwat – application to human skin, having mites present; if the mites are the only agent eliciting the signs recognizable as stuggicient to invoke the instant methods, Bhagwat does not acknowledge them, thus renders the instant method steps. The prior art, how ever does so suggest at Merck, Robinson – However, and symptoms addressed by Bhagwat to be the basis for Bhagwat's to be the basis for Bhagwat's methods of administering sulfur and sulfacetamide. There is no patentable distinction evident.

Claims 1-3, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Merck – '72 p.).

See Scabies, P. 1455 – Sulfur + Neomycin sulfate, ointments, washing is required; starch baths.

Claims 1-3, 5-8, 10, 12, 16, 116, 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson or White 1894, in view of Allen – 4895727 and declaration of Patel.

Robinson, (above) and white (p. 228, 230 external) show sulfphur and sulphurated line, is applied as instantly claimed, to kill mites. Robinson teaches sulphur

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and suitable carriers, and washing of the skin, to treat mites, but neither teach the combination with sulfacetamide. However, Allen teaches the desirability of (summary) enhancing active agents, inclusive of antiparasitic agents (col. 3, lines 39-42) and antimicrobial agents, for mites (8., col. 5), with application of zinc sulfate (col. 2, line 4-6). Claim 14 shows the method of claims 12, enhancing skin penetration of anti parasitic agents (without reservation, thus, inclusive of the Robinson, White Sulphur) by administering zinc sulfate. Sulfurated lime (claim 3) is also specifically mentioned as an agent enhanced by zinc sulfate, as are other sulfides, sulfates, sulfoxides, sulfuric acids, sulfonamides, sulfones thiosulfates and sodium sulfacetamide.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an effective antiparasitic treatment for scabies, to employ that or Robinson or White; sulphur sulphurated lime or Sulphur iodide. Motivation to add zinc sulfate is taught by Allen, showing enhanced effects when sulfate is added. Allen indicates suitable topical carrier and delivery forms are known in the art: lotions, creams, gels (col. 6, lines 57-66). White addresses the issue of sulphur – caused irritation (p. 228, external top) – Thus, obvious to wash off; Robinson, shows this Patel's declaration indicates one in the art would know to formulate sulfides, sulfuric acid to provide dermatologically acceptable compositions, thus rendering the instant claims to approximately normal pH within the acceptable range, and not of patentable weight. Likewise, Demodex is seen as within the range of parasitic agents, and not excluded as treatable by White/ Robinson, since these genera have not been shown to be critical by applicant.

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Claims 1-3, 18, 116 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Robinson '39 explained by White, 1894.

Robinson teaches the instant method of treating scabies by application of sulphur ointment (p. 638, col. 2). The ointment is made from precipitated or sublimed sulphur. This is not further described, but White shows it to contain sulphurous and sulphuric acids as impurities of sub claimed sulphur, and lime sulphate as impurity of precipitated sulphur (p.227). Thus, the sulphur of Robinson, applied as pharmacologically dictated includes sulfur derivatives of the instant claims. There is no other active required by Robinson.

Applicant's arguments filed on 11/23/05 have been fully considered but they are not persuasive. Applicant's arguments and amendments have been considered in the above rejections; where persuasive, rejection, have been dropped.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (571) 272-0619. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gray Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Levy/LR
March 10, 2005

A handwritten signature in black ink, appearing to read 'Neil S. Levy', written in a cursive style.

NEIL S. LEVY
PRIMARY EXAMINER